**Medical Alley**®
A COLLABORATIVE FORUM WHICH PROMOTES AN ENVIRONMENT TO ENHANCE INNOVATION IN HEALTHCARE

'99 NOV 30

November 22, 1999

Dockets Management Branch HFA-305
Food and Drug Administration
5630 Fishers bane, Room 1061
Rockville, MD 20852

RE: Docket Number: 99D- 12 1

To whom it may concern:

On behalf of Medical Alley, and specifically its Medical Device Work Group, I am providing these comments in response to the draft guidance entitled, Evidence Models for the Least Burdensome Means to Market," (Docket Number: 99D-121) which were published in the September 1, 1999 Federal Register, We appreciate the opportunity to offer our reaction to this draft guidance.

*Overall reaction - Key* area ***for improvement***

Our first and overriding reaction to this document is that it does not provide those who may need to submit clinical data to CDRH/ODE with a useable framework for deciding which data collection method will provide the Agency with the information it needs while limiting the burden on the data collector. It is our perspective that the guidance is not useable because it does not address how the varying levels and sources of valid scientific evidence provided for in the regulation can be utilized. In sum, we find the draft guidance to be abstract and impractical.

While the Secretary has put significant effort into describing randomized controlled clinical trials and their role in data collection, the focus on this data collection pathway to the virtual exclusion of all others fails to effectively acknowledge the many considerations inherent in the development and use of medical devices. We believe that the most significant improvement which could be made to this guidance document is inclusion of language which addresses how a manufacturer should consider whether a randomized, controlled clinical trial or one of the many other data collection pathways is the most appropriate and least burdensome pathway to generating the information that allows the Agency to make an informed decision. Further, this improvement should start by describing when it is appropriate to use the most fundamental of the data collection methods and go on from there to describe when more elaborate methods are warranted. Given that methods other than randomized controlled trials have been utilized and accepted by the Agency in the past, and that these methods have a track record of effectively demonstrating that a product merits being allowed on the market, we believe that they still have a substantial role to play in today's regulatory environment.

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In any event, future versions of this guidance should take the form of a series of questions and/or a flow chart that will help the manufacturer determine which method is the least burdensome and most appropriate for their products.

*Other ureas that should be addressed in the guidance*

We also believe that the failure of the draft guidance to more fully address 510(k)s and IVDs needs to be addressed in future revisions. We feel this is especially true since IVDs have been addressed in both the 510(k) and PMA modification guidance documents. Prom our perspective, there is no reason why they can not also be addressed in this guidance document which cuts across product categories.

In addition, given the legislative goal of achieving the least burdensome means to gaining the information, the Agency should address how manufacturers can use clinical information which is already in the public domain -- even if that information was not created by the manufacturer who is making a submission. Finally, we believe that the guidance document should acknowledge and incorporate the role of the pre-meeting provisions that were included in FDAMA.

*Summary*

We applaud the Agency's efforts, through its stakeholder meeting and this first draft of the least burdensome guidance document, to begin the development of a workable approach to determining the most appropriate data collection method to gain the FDA's permission to enter the market. Similarly, as subsequent steps are taken we believe it is important that the efforts and comments of the Least Burdensome Task Force, a coalition of organizations interested in improving the draft guidance, be acknowledged, carefully considered and utilized as the Agency works to further refine the guidance.

As stated above, we believe the draft guidance document needs substantial revisions in order to be usable to medical product manufacturers. We strongly urge the Agency to create a task force, made up of Agency staff and representatives of the relevant external stakeholders, to collaboratively develop a workable guidance document that meets all parties' interest in an effective and efficient approach to the collection of data. Medical Alley stands ready to be of assistance in that effort in whatever way you deem appropriate.

We thank you for your consideration of our views.

Sincerely,

Thomas L. Meskan
President

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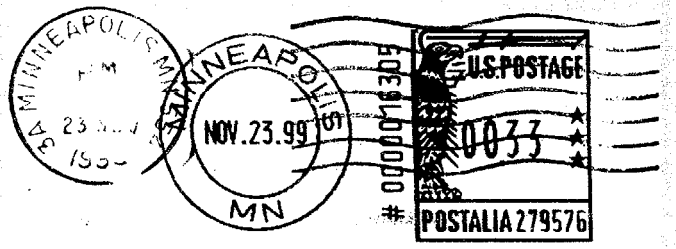


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RE: Document # 99D-2873